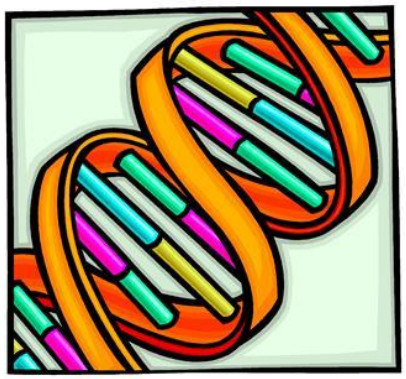
Japanese View about Subject Matter Eligibility of Gene Patents

-Should the bar be raised? -



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Shimako Kato

Provisions on “Invention”

Article 1 (Purpose)

The purpose of this Act is, through the protection and the utilization of inventions, to encourage inventions, and thereby to contribute to the development of industry.

Article 2 (Definition)

(1) “Invention” in this Act means creation of technical ideas of a high level which utilizes law of nature.

Article 29, main paragraph

An inventor of industrially applicable inventions may be entitled to obtain a patent for the said invention…”

*The inventions must be completed.

What is not deemed an “invention”?

(1) A law of nature as such

(2) Mere discoveries nothing to do with creations

ex. natural resources which are not created by inventor consciously using technical idea

(3) Those contrary to a law of nature

(4) Those which do not utilize a law of nature

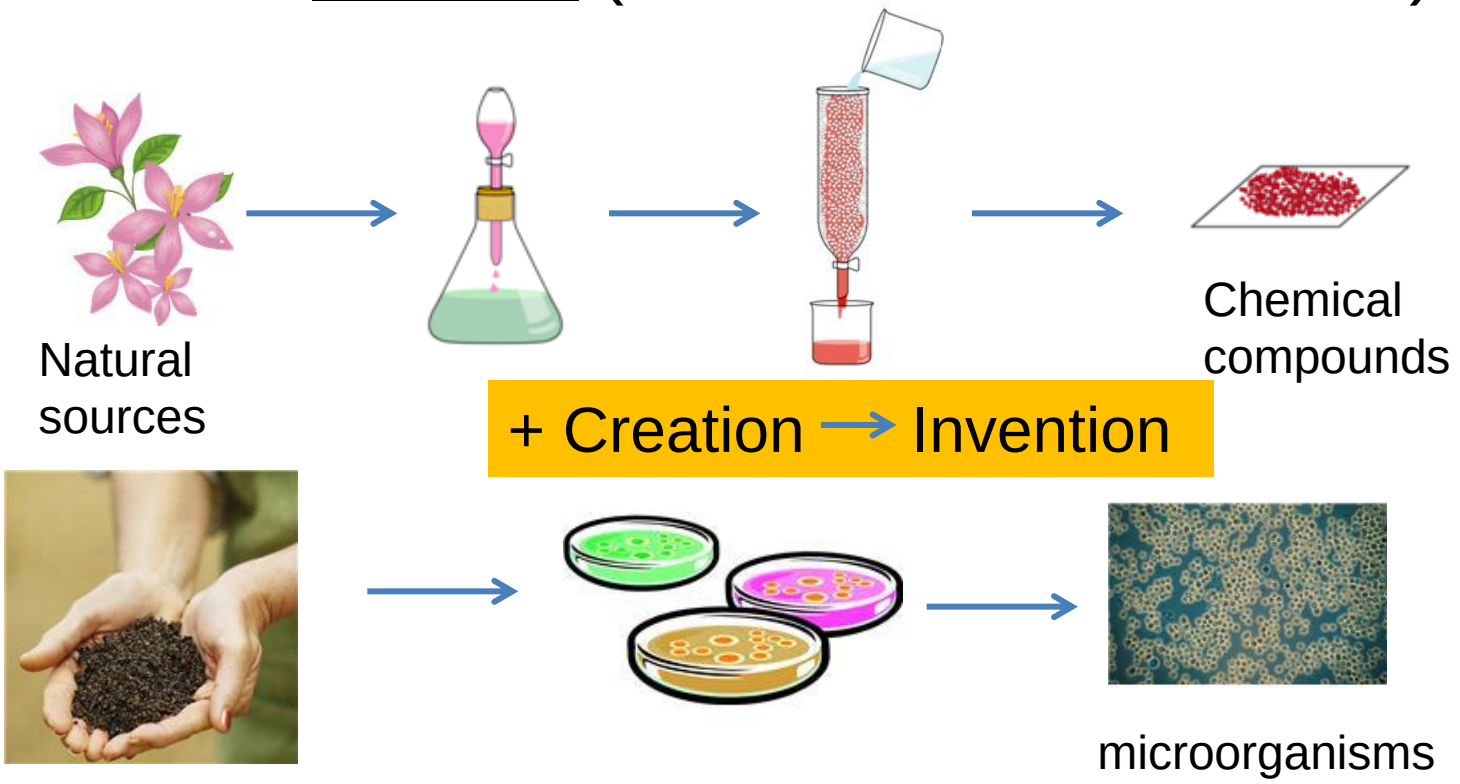
(5) Those not deemed as technical ideas

(6) Those which clearly impossible to solve the problem by any means presented in a claim

(Examination Guidelines)

Exception for “mere discoveries”

- Chemical compounds and microorganisms, etc. <u>which are artificially isolated from natural sources</u> are deemed as “invention”, because they are outcomes of <u>creation</u>.(Examination Guidelines)



Biotechnological Materials

- In case where an invention is directed to gene, vector, transformed vector, transformant,…, if its usefulness is not described in the specification and the usefulness can not be figured out from it, the invention is deemed as industrially inapplicable invention. (Examination Guidelines)

pathogenesis of leukemia

+ Usefulness → Invention

- Description of "usefulness" is also a requirement of enablement.

Decisions on eligibility of gene patent(1)

"Peptide having increased sodium discharge activity case" (Judgment on March 13, 2001 by the Tokyo High Court)

- Definition for the peptide in the claim is broad. (Sequence of 17 amino acids (Sequence A) was specified, but various length of amino-acid sequence can be further added to the Sequence A .)
- Increased sodium discharge activity of human BNP-26 and BNP-32 are only described. (only two embodiments)
- The applicant tried to prove all claimed amino-acid sequences having "Sequence A" have the discharge activity by submitting expert opinions but in vain.

Ruling: The invention has not yet been completed, because the activity of all claimed peptides was not proved.

Decisions on eligibility of gene patent(2)

"Nucleic acid encoding body weight modulator case"
(Judgment on October 19, 2005 by the IP High Court)

Basic idea of "invention" in case of gene was ruled:

" Generally, the nature of invention of a chemical compound is to provide a new and industrially applicable chemical compound. However, when the chemical compound is a natural source like a gene, clarifying and confirming its existence is deemed mere discovery. Even if a substance is isolated from natural source and some processes are added to it, it does not mean that industrially applicable chemical compound is provided. By clarifying its usefulness and adding a new technical perspective, it is deemed as completed industrially applicable invention."

Decisions on eligibility of gene patent(3)

“Polynucleotide encoding chemokine receptor 88C case” (Judgment on October 6, 2008 by the IP High Court)

- Infringement case over peptide patent.

- The patent was found invalid based on lack of novelty. (Priority was not granted, due to lack of enablement and industrial applicability, i.e., usefulness in the original application.)

“ In the original application, any chemokine (ligand) which bind to chemokine receptor 88C (CCR5) is not specified. It means that the function of 88C is not described. Therefore the invention is not industrially applicable.”

Should the bar be raised ?

Issues over patents of biotechnological materials

(1) Broad claim (ex. reach-through claim, *in-silico* screening process)

- Enablement
- Ineligible based on another reason (ex. databases of compounds defined by *In-silico* screening)

(2) Scope of the patent

"Usefulness" is necessary but not obliged to be described in the claim.

→ Other use of patented gene can be covered?

- Claim construction
- Clarity of claim

(3) Public policy

Risk of preventing basic research

- Matter of licensing
- Compulsory license (if necessary)
- Limited relief

Thank you!

Shimako Kato

Patent Attorney

Abe, Ikubo &Katayama

E-mail: shimako.kato@aiklaw.co.jp